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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,055	11/09/2001	Benjamin R. Yerxa	03678.0023.CNUS04	8525

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HOWREY SIMON ARNOLD & WHITE, LLP
C/O M.P. DROSOS, DIRECTOR OF IP ADMINISTRATION
2941 FAIRVIEW PK
BOX 7
FALLS CHURCH, VA 22042

EXAMINER

LEWIS, PATRICK T

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 12/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,055

Applicant(s)

YERXA ET AL.

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II in the reply filed on July 8, 2003 is acknowledged.

Applicant's Response dated September 13, 2004

2. In the Response filed September 13, 2004, claims 1, 4, and 10-11 were amended.
3. Claims 1-11 are pending. An action on the merits of claims 1-11 is contained herein below.
4. The rejection of claims 1-9 under 35 U.S.C. 112, second paragraph, has been rendered moot in view of applicant's amendment dated September 13, 2004.
5. The rejection of claims 1-11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of US 5,900,407 has been rendered moot in view of the Terminal Disclaimer filed June 17, 2004.
6. The provisional rejection of claims 1-11 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4, and 7-15 of copending Application No. 10/041,826 is maintained for the reasons of record set forth in the Office Action dated March 17, 2004.

Rejections of Record Set Forth in the Office Action dated March 17, 2004

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
8. Claims 1-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2, 4, and 7-15 of copending Application No. 10/041,826. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The difference between the instantly method and the method of the '826 application is that the '826 application is drawn to a method of enhancing drainage of the lacrimal system; however one of ordinary skill in the art at the time of the invention would have a reasonable expectation of success of enhancing drainage of the lacrimal system employing the method of the instant application since both methods employ the same nucleotide (compound of Formula II) and methodological steps (administration of a compound of Formula II to the eyes). Likewise, one of ordinary skill in the art at the time of the invention would have a reasonable expectation of success in employing the method of the '826 application to stimulate tear secretion and mucin production in the eye. Although the two inventions are drawn to a different effect, they are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Applicant's arguments filed September 13, 2004 have been fully considered but they are not persuasive. Applicant argues that a method of stimulating tear secretion

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and a method of enhancing drainage of the lacrimal system are opposite mechanisms and achieve opposite results.

Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. In construing process claims and references, it is the identity of manipulative operations which leads to finding of double patenting. In the instant case, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. The method of the '826 application comprises administering a compound of Formula II to the eyes as instantly claimed. The stimulation of tear secretion and mucin production is not an active methodological step in the process but is rather a consequence of the interaction between the nucleotide and eye.

Conclusion

10. Claims 1-11 are pending. Claims 1-11 are rejected. No claims are allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick T. Lewis, PhD
Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

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